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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/533,080	04/28/2005	Kazuhiko Kato	271511US0PCT	2324

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1940 DUKE STREET
ALEXANDRIA, VA 22314

EXAMINER

MAEWALL, SNIGDHA

ART UNIT	PAPER NUMBER
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1612

NOTIFICATION DATE	DELIVERY MODE
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09/28/2009

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No. 10/533,080	Applicant(s) KATO ET AL.	
	Examiner Snigdha Maewall	Art Unit 1612	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 03 April 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-9 is/are pending in the application.
- 4a) Of the above claim(s) 8 and 9 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-7 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>07/20/05</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

The reference by Yamagishi et al, (Application No. JP 02-222707) used in the previous Office Action had typographical error. The correct Application No. is (JP 2000-222707).

The reference by Yamagishi et al, (Application No. JP 2000-222707) used in the previous Office Action was inadvertently not cited in PTO 892. A new Office Action is being made with correct reference no. (Application No. JP 2000-222707).

Summary

1. Receipt of IDS filed on 07/20/05 is acknowledged.

Restriction/Election

Applicant's election with traverse of Group 1, claims 1-7 in the reply filed on 04/03/09 is acknowledged. The traversal is on the ground(s) that the two groups are not distinct inventions and there is no search burden on the examiner. Applicant's arguments are not persuasive because the invention 1 comprises an oral formulation where as invention II comprises specific chewing gum composition. The groups comprise fluoride and acid as specific components which provide specific property to the composition. The inventions listed as Groups I and II do not relate to a single

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general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: Group I and Group II do not have a common technical feature that distinguishes the claims over the prior art. The common technical feature found in both groups is the oral formulation with fluoride and acid which is disclosed in the prior art by Rajaih (WO 02/074274). Thus, the technical feature is lacking unity since the oral formulation is not a technical feature that defines a contribution over the prior art as evidenced by Rajaih.

The requirement is still deemed proper and is therefore made FINAL.

Claims 8-9 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 04/03/09.

Claims **1-7** are under prosecution.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

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A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

3. Claims 1-4 are rejected under 35 U.S.C. 102(b) as being anticipated by Ochiai et al. (USP 4,363,794).

Ochiai et al. discloses an oral composition comprising sodium fluoride and an acceptable acid such as tartaric acid, lactic acid, citric acid or ascorbic acid and water, see abstract and examples. The reference teaches pH of the preparation in a range of 2 to 4, see column 2, lines 52-53. The reference teaches sodium fluoride and lactic acid, see example 6. The amounts of sodium fluoride are 0.145% and the amount of lactic acid is 1.0% in example 6. Various salts with potassium such as potassium fluoride and potassium mono fluorophosphates are disclosed in column 4, lines 25-35. Regarding the limitation, when the oral preparation is applied to the teeth, a light scattering layer is formed is an intended function and since Ochiai teaches the same composition, one would expect similar property when applied.

4. Claims 1-5 are rejected under 35 U.S.C. 102(e) as being anticipated by US Publication (US 2003/0124065 A1) by Majeti et al.

Majeti et al. teaches oral composition providing enhanced overall cleaning, methods of cleaning, whitening and polishing teeth see abstract. The reference teaches sodium fluoride and tartaric acid, see paragraph [0081] and [0087 and 0088]. Fluoride

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ion concentration is disclosed from 0.005% to 5.0%. The amount of tartaric acid is disclosed to be from 0.1% to 2.5%, see paragraph [0082] on page 7. Water soluble alkali metals such as sodium potassium salts can also be mixed, see paragraph [0037]. Teeth whitening active such as potassium chlorite is disclosed in paragraph [009].

Regarding the limitation, when the oral preparation is applied to the teeth, a light scattering layer is formed is an intended function and since Majeti teaches the same composition, one would expect similar property when applied.

5. Claims 1-4 are rejected under 35 U.S.C. 102(b) as being anticipated by Yamagishi et al. (JP 2000-222707) published 06/02/02).

Yamagishi teaches a composition for oral cavity making teeth white, smooth and glossy see title. The composition comprises either itself or 30% aqueous solution of fluorine compound in an amount of 0.02 to 0.7 wt. % and acidic compound having pka of 2.5-6.0 in an amount from 0.1 to 10.5 mol/kg, see abstract. Claim 1 teaches pH from 3 to 5.5 and acid to be from malic acid to tartaric acid, see claims 1-3. The reference teaches lactic acid, acetic acid, malic acid, since the pH of the composition is shown to be 3, and the presence of acidic compound is therefore evident.

Regarding the limitation, when the oral preparation is applied to the teeth, a light scattering layer is formed is an intended function and since Majeti teaches the same composition, one would expect similar property when applied.

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Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. Claims 6-7 are rejected under 35 U.S.C. 103(a) as being unpatentable over US Publication (US 2003/0124065 A1) by Majeti et al.

Majeti et al. teaches oral composition providing enhanced overall cleaning, methods of cleaning, whitening and polishing teeth, see abstract. The reference teaches sodium fluoride and tartaric acid, see paragraph [0081] and [0087 and 0088]. Fluoride ion concentration is disclosed from 0.005% to 5.0%. The amount of tartaric acid is disclosed to be from 0.1% to 2.5%, see paragraph [0082] on page 7. Water soluble alkali metals such as sodium potassium salts can also be mixed, see paragraph [0037]. Teeth whitening active such as potassium chlorite is disclosed in paragraph [009].

The reference teaches the overlapping ranges of the claimed components. The reference does not teach the claimed light scattering layer formed inside the enamel of teeth, however such property is associated with the chemical composition and the prior art makes obvious the claimed components. The prior art does not disclose the exact claimed values, but does overlap: in such instances even a slight overlap in range establishes a *prima facie* case of obviousness. In re Peterson, 65 USPQ2d 1379, 1382 (Fed. Cir. 2003). Alternately optimization of amounts would have been within the

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purview of skilled artisan by doing experimental manipulations at the time of instant invention.

8. Claims 5-7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ochiai et al. (USP 4,363,794) in view of Publication (US 2003/0124065 A1) by Majeti et al.

The teachings of Ochiai have been cited above. The reference does not teach potassium salts.

Majeti et al. teaches oral composition providing enhanced overall cleaning, methods of cleaning, whitening and polishing teeth see abstract. The reference teaches sodium fluoride and tartaric acid, see paragraph [0081] and [0087 and 0088]. Fluoride ion concentration is disclosed from 0.005% to 5.0%. The amount of tartaric acid is disclosed to be from 0.1% to 2.5%, see paragraph [0082] on page 7. Water soluble alkali metals such as sodium potassium salts can also be mixed, see paragraph [0037]. Teeth whitening active such as potassium chlorite is disclosed in paragraph [009].

It would have been obvious to one of ordinary skill in the art to have added potassium ions in the teachings of Ochiai et al. in order to increase dental whitening effect motivated by the teachings of Majeti et al. Generally, it is *prima facie* obvious to select a known material for incorporation into a composition, based on its recognized suitability for its intended use. See MPEP 2144.07.

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9. Claims 5-7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yamagishi et al. (JP 2000-222707) published 06/02/02) in view of US Publication (US 2003/0124065 A1) by Majeti et al.

Yamagishi teaches a composition for oral cavity making teeth white, smooth and glossy, title. The composition comprises either itself or 30% aqueous solution of fluorine compound in an amount of 0.02 to 0.7 wt. % and acidic compound having pka of 2.5-6.0 in an amount from 0.1 to 10.5 mol/kg, see abstract. Claim 1 teaches pH from 3 to 5.5 and acid to be from malic acid to tartaric acid, see claims 1-3.

The reference does not teach potassium ions. Majeti teaches potassium ions while teaching tooth whitening composition. It would have been obvious to one of ordinary to substitute potassium ions in the teachings of primary reference in order to increase tooth whitening motivated by the teachings of secondary reference. Since the references teach tooth whitening, it is the position of the examiner that due to the whitening effect a light scattering layer would be formed as claimed because the claimed components of the composition are taught by the prior art and one skilled in the art would expect the property of light scattering effect to be associated with the chemical composition of the formulation absent evidence to contrary. Optimization of amounts would have been within the purview of skilled artisan by doing experimental manipulations at the time of instant invention.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Snigdha Maewall whose telephone number is (571)-

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272-6197. The examiner can normally be reached on Monday to Friday; 8:30 a.m. to 5:00 p.m. EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Frederick Krass can be reached on (571) 272-0580. The fax phone number for the organization where this application or proceeding is assigned is 571-273-0580.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Snigdha Maewall/

Examiner, Art Unit 1612

/Gollamudi S Kishore/

Primary Examiner, Art Unit 1612